PATENT
Docket N . 273102007800 #26

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office (703) 308-6916, Attn: Office of Petitions, on May 31, 2002.

Nora Durant

Nora Durant

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Hans BOEHRINGER, et al.

Serial No.: 08/812,616

Filing Date: March 6, 1997

For: QUANTITATIVE LATERAL FLOW ASSAYS AND DEVICES

Examiner: C. Chin

Group Art Unit: 1641

FAX RECEIVED
MAY 31 2002
PETITIONS OFFICE

RENEWED PETITION UNDER 37 C.F.R. § 1.137(b) / REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.137(e)

Commissioner for Patents
Washington, D.C. 20231
Attn: Office of Petitions

Dear Sir:

Applicants respectfully request reconsideration of the Decision on Petition, mailed April 24, 2001, and revival of the above identified application. The application was unintentionally abandoned for failure to submit a proper response to the Office action mailed September 1, 2000. The entire delay in filing the required reply from the due date for the reply until the filing of the grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional. A Notice of Appeal accompanies this request.

As the Decision on Petition was mailed April 24, 2001 and the present Request for Reconsideration is dated and faxed on May 30, 2002, this request is considered timely filed.

Exhibits A–F are hereby attached as part of the present request f r reconsideration.

I. Applicant's Asserti ns

The Applicants base the present request to revive, in part, on the following three assertions:

(1) In the Decision on Petition to Revive, mailed April 24, 2002, denying the Petition to Revive, the Office of Petitions stated that the Applicants had failed to reply to a final Office action;

(2) The record as a whole indicates that the only outstanding Office action in the above identified matter is a non-final Office action; and

(3) The Applicants complied with the standard for a Petition to Revive in the Petition mailed November 7, 2001.

II. The Relevant Prosecution Record

A Continued Prosecution Application (CPA) under 37 C.F.R. § 1.53(d) was mailed by Applicants on January 21, 1999. A Response to Missing Parts pertaining to the CPA was mailed on November 29, 1999 and received by the USPTO on December 2, 1999.

A preliminary amendment was mailed by Applicants on January 3, 2000. In this amendment claims 2, 3, 24-52, 54-55, 64 and 82-119 were canceled, claims 1, 8, 10, 15, 23, 53, 56-63, 65-71, 73-81 and 120 were amended, and claims 121-125 were added.

A final Office action was mailed by the USPTO on February 23, 2000 (attached hereto as **Exhibit A**). This final Office action indicated that it was in response to the communication filed December 2, 1999 and, therefore, did not account for the preliminary amendment mailed on January 3, 2000.

On September 1, 2000 a **non-final** Office action was subsequently mailed by the USPTO (attached hereto as **Exhibit B**). In this Office action, there were three clear indications that the action was not final: First, the "final action" box was not checked on the Office Action Summary page; second, Examiner Chen stated that "[t]he office action dated 2/23/00 is vacated in favor of the following ffice action" (See page 1); and third, there was no language in the conclusion of

the Office action which characterized this action as a final action (compare the conclusion section of **Exhibits A and B**).

The Applicants mailed a response to the September 1, 2000 Office action, accompanied by the appropriate extension fee, on March 1, 2001.

III. The Holding of Abandonment

A Notice of Abandonment was mailed on May 8, 2001 indicating that no response was received in response to the Office action of September 1, 2000 (See Paper 18).

A petition to withdraw the holding of abandonment, under 37 C.F.R. § 1.181(a), was subsequently mailed by the Applicants on June 25, 2001. This petition indicated that a response to the non-final Office action was in fact submitted on March 1, 2001.

A Decision on the above petition was mailed by the USPTO around August 23, 2001 (attached hereto as **Exhibit C**). In this decision, the petition to withdraw the holding of abandonment was denied. However, in this decision the following determinations were made: (1) "[o]n September 1, 2000, a non-final Office action was mailed to applicants which vacated the February 23, 2000 Office action;" (2) the response mailed March 5, 2001 (referred to above as the response filed March 1, 2001) was received and timely filed; and (3) the response of March 5, 2001 was considered not fully responsive to the non-final Office action of September 2000.

In response to this decision, Applicants mailed a Petition to Revive, under 37 C.F.R. § 1.137(b), for unintentional abandonment on November 7, 2001 (attached hereto as **Exhibit D**). An Amendment, which is distinct from the Applicant's response of March 1, 2001, and is earnestly believed to be a *bona fide* response to the non-final Office action of September 1, 2000, accompanied that petition (attached hereto as **Exhibit E**).

The Petition to Revive was dismissed by the Office of Petitions in an decision mailed April 24, 2002 (attached hereto as **Exhibit F**). In this decision, the Office of Petitions appears to have interpreted the Office action f September 1, 2000 as a final Office acti n. Respectfully, as indicated ab ve, the evidence indicates that this was a non-final Office action. The Office action

of September 1, 2000 had no indication of finality, and, furthermore, it specifically withdrew and replaced the earlier Office action dated February 23, 2000.

As provided in MPEP § 711.03(c), the reply requirement of a petition to revive varies as to whether there is a final or non-final Office action outstanding. Due to the apparent interpretation by the Office of Petitions that a final Office action was outstanding in the above identified matter, the Office held the reply submitted as insufficient. Respectfully, because the only outstanding action in this matter was not a final (nor supplemental to a final) action, the standard for the response component of a petition to revive was met in the petition mailed on November 7, 2001.

Also, according to MPEP § 711.03(c), the required reply to a non-final action in a nonprovisional application abandoned for failure to prosecute may be either (1) an argument or amendment under 37 C.F.R. § 1.111, **OR** (2) the filing of a continuing application under 37 C.F.R. § 1.53(b) (or a continued prosecution application under 37 C.F.R. § 1.53(d)).

Respectfully, a brief perusal through the Amendment submitted with the Petition to Revive, mailed November 7, 2001, reveals that the reply is a *bona fide* response to the non-final Office action of September 1, 2000 (compare **Exhibits A and E**). The Applicants should not be required to submit a notice of Appeal, nor a continuing application or CPA in response to a non-final Office action. The submitted Amendment clearly addresses each of the Examiner's points in the Office action mailed September 1, 2000; and, moreover, the sufficiency of the Amendment should be weighed after revival of the application.

Therefore, the Applicants respectfully assert that the Petition to Revive, as mailed on November 7, 2001, was complete as filed. Reconsideration of the decision denying this petition is respectfully requested based upon the record as a whole.

IV. Telephone Calls to the Office of Petitions and Primary Examiner on May 21, 2002

In an effort to determine the exact nature of the reasons underlying the denial of the Petition to Revive, on May 21, 2002, Applicants' authorized representative, Ms. Karen Dow,

placed a call to Examiner Congo at the Office of Petitions. During this call, Examiner Congo asserted that the USPTO - PALM system indicated that the Office action dated September 1, 2000 was a Supplemental to the Final Action. Ms. Dow then indicated that the Office action of September 1, 2000 explicitly vacated the Office action of February 23, 2000. In response, Examiner Congo indicated that Examiner Chin should be contacted to resolve the apparent conflicts surrounding this issue.

Ms. Dow proceeded to contact Examiner Chin. Examiner Chin indicated that the Applicants should comply with the requirements of, or otherwise work the situation out with, the Office of Petitions. Without the aid of the file, which was presumably with the Office of Petitions, Examiner Chin indicated that the Petitions group is supposed to review the file prior to making a decision. In addition, Examiner Chin also seemed to think that the September 1, 2000 Office action was the latest action in this matter, and that this action was probably not final.

Ms. Dow then contacted Examiner Congo to follow-up on her earlier call. During this call, Examiner Congo indicated that a Renewed Petition to Revive could be forwarded to his attention via facsimile.

V. Request For Reconsideration Requirements

In the Decision on Petition, mailed April 24, 2002, the Office of Petitions provided the elements of a grantable petition under 37 C.F.R. § 1.137(b). Based on these elements, the Office has indicated that "[a]ny renewed petition should be accompanied by a proper reply in the form of a Notice of Appeal, the filing of a continuation application or a RCE." Further, the Office has warned that a failure to include any of these elements in a reply to the decision mailed April 24, 2002 "will be construed as an intentional delay in presenting a grantable petition."

Although Applicants respectfully disagree with the determination that the outstanding Action in this matter is a final action, and with the response requirements of the Office of Petitions presented in the Decision on Petition, the Applicants nevertheless desire to comply with the instructions of the Office of Petitions. Therefore, a Notice of Appeal, along with the required fe , accompanies this Request for Reconsideration. However, if the decision on this Request for

Reconsideration results in the revival of the above identified application, which revival does not require the Notice of Appeal, the Applicants respectfully and formally present the following two requests: (1) a request for the refund of the appeal fee accompanying the present Notice of Appeal, and (2) a request to abandon the present Notice of Appeal. The Applicants consider these requests to be reasonable based upon the facts involved in the present matter and do not believe they should be charged the appeal fee.

VI. Conclusion

Based on the foregoing, Applicants respectfully request reconsideration of the denial of Applicant's earlier submitted Petition to Revive the above identified application. Further, the Applicants renew the request to revive this application based upon the petition submitted by Applicants on November 7, 2001.

If the Examiner has any questions, please feel free to call the undersigned, Karen Dow, at (858) 720-7960 or send a facsimile at (858) 720-5125.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 273102007800.

Respectfully submitted,

Dated: May 30, 2002

By: Karen Babyak Dow

Karen B. Dow
Registration No. 29,684

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1204 A-0105CIP

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

KBDow/KGB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/812,616	03/06/97	BUERRINGER H	1204A-0105CIP

HM22/0223

TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
CHIN, C	
ART UNIT	**PAPER NUMBER**
1641	13

DATE MAILED: 02/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Amend/Appeal Due 5-23-00 ns

TOWNSEND & TOWNSEND & CREW
00 FEB 29 AM 8:23
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PTO-90C (Rev. 2/95) 2 - Mail Copy

Office Action Summary	Application No. 08/812,616	Applicant(s) Boehringer
	Examiner Chris Chin	Group Art Unit 1641

☒ Responsive to communication(s) filed on *Dec 2, 1999*

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-120* is/are pending in the application.

Of the above, claim(s) *24-52 and 82-119* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9, 11-14, 16-22, 53-61, 63-68, 70-78, 80, 81, and 120* is/are rejected.

☒ Claim(s) *10, 15, 23, 62, 69, and 79* is/are objected to.

☒ Claims *1-120* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 1/21/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/812,616 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

2. Applicant's election with traverse of Group I in Paper No.6 is acknowledged. The traversal is on the ground(s) that some of the groups are classified in the same class and subclass and thus would not create an undue burden on the examiner. This is not found persuasive because even though some of the groups are placed in the same class and subclass, the search for each of the groups require a different search strategy on commercial data bases since they recite some limitations that do not overlap. However, upon further consideration, claims 16-23, 53-81 and 120 will be examined along with claims 1-15 of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-23, 53-81, and 120 will be examined. Claims 24-52 and 82-119 are non-elected.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 U.S.C. § 112

4. Claims 8, 58, 64, and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague because the recitation of "an ligand" is grammatically incorrect. Reciting --a ligand-- would obviate this rejection.

Claims 58 and 71 are confusing because they do not refer to a previous claim from which they depend, i.e. claim 58 cannot depend from claim 59.

Claim 64 is vague and indefinite. The recitations of "the ligand" and "the receptor" lack antecedent support.

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date f application for patent in the United States.

6. Claims 1, 2, 5, 6, 13, 14, 53, 54, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Lou et al.

Lou et al (Clin. Chem. 39/4, 619-624, 1993) disclose a method and chromatographic test strip for detection and quantitation of lipoprotein a (Lp(a)). As shown in Figure 1, the test strip comprises a sample loading area, conjugate pad, measurement region, and an end of assay indicator. The conjugate pad contains diffusible Lp(a) coated colloidal selenium particles. The measurement region contains immobilized monoclonal antibodies specific for Lp(a). The antibodies are positioned in the measurement region in a ladder-bar format. An end of assay indicator is located at the end of the test strip. In use, the number of ladder bars shown in the measurement region provides an indication of the amount of Lp(a) present - see pages 619-621.

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al.

See above for the teachings of Lou et al.

Lou et al differ from the instant invention in failing to teach configuring the disclosed test strip for sandwich immunoassays.

Maggio et al teach the advantages and disadvantages of competitive and sandwich immunoassays. Sandwich immunoassays obviate the need for antigen reagents which are required for competitive immunoassays (page 61). The antigen reagent in competitive immunoassays must be as pure as possible. Unlike in sandwich immunoassays where the labeled reagent is a labeled antibody which does not have to be highly purified (pages 184-185).

It would have been obvious to one of ordinary skill in the art to configure the test strip of Lou et al for sandwich immunoassays as taught by Maggio et al because Maggio et al teach that sandwich immunoassays provide the advantage of obviating the need for an antigen reagent. such as the Lp(a) required for the Lp(a) coated selenium particles in the conjugate pad of Lou et al. By configuring the test strip of Lou et al for a sandwich immunoassay, there would be no need for purification procedures to obtain highly purified Lp(a).

With respect to claim 120, it would have been obvious to one of ordinary skill in the art to place the test strip of Lou et al (or Lou et al as modified by the teachings of Maggio et al) in a test kit arrangement because test kits are well known in the art for their recognized advantages of convenience and economy.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Weng et al.

See above for the teachings of Lou et al.

Lou et al differs from the instant invention in failing to teach the use of particles to indirectly immobilize the antibodies in the capture zone(s) of the test strip.

Weng et al (U.S. Patent 4,740,468) teach the use of particles to indirectly immobilize antibodies to a specific reagent zone of a chromatographic test strip (col. 13, line 50, to col. 14, line 68).

It would have been obvious to one of ordinary skill in the art to use particles, as taught by Weng et al, to immobilize the antibodies in the capture zone of Lou et al's test strip because Weng et al show it to be conventional in the art to immobilize antibodies to a chromatographic test strip via the use of particles. Moreover, particles provide the advantage of increased surface area so that more antibodies can be immobilized to the capture zone.

10. Claims 20, 59, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Weng et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach the use of particles to indirectly immobilize the antibodies in the capture zone(s) of the test strip.

See above for the teachings of Weng et al.

It would have been obvious to one of ordinary skill in the art to use particles, as taught by Weng et al, to immobilize the antibodies in the capture zone of the test strip of Lou et al, as modified by the teachings of Maggio, because Weng et al show it to be conventional in the art to immobilize antibodies to a chromatographic test strip via the use of particles. Moreover, particles provide the advantage of increased surface area so that more antibodies can be immobilized to the capture zone.

11. Claims 71 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Kang et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach a multi-test strip embodiment wherein all of the test strips contact a common sample receiving zone.

Kang et al (U.S. Patent 5,559,041) disclose a multizone chromatographic test strip for performing sandwich or competitive immunoassays. Figure 5 shows an embodiment wherein multiple test strips are configured around a common sample receiving zone (310) for the purpose of assaying for one or more analytes in a given sample (col. 4, line 67, to col. 5, line 21).

It would have been obvious to one of ordinary skill in the art to configure the test strips of Lou et al around a common sample receiving zone as taught by Kang et al because Kang et al

teaches that such a configuration provides the advantage of being able to perform multiple assays on the same sample for one or more desired analytes.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Katz et al.

See above for the teachings of Lou et al.

Lou et al differs from the instant invention in failing to teach the use of ligand/receptor system to immobilize the antibodies in the capture zone of the test strip.

Katz et al (U.S. Patent 4,496,654) teaches the use of an avidin/biotin system for immobilizing antibodies to a solid support. Avidin is first immobilized to a solid support. Biotinylated antibodies are then applied to the avidin coated solid support. The biotin portion of the biotinylated antibodies binds to the avidin to immobilize the antibodies to the solid support.

It would have been obvious to one of ordinary skill in the art to use the avidin/biotin system of Katz et al to immobilize the antibodies in the capture zone of the test strip of Lou et al because the highly specific affinity avidin for biotin provides for improved immobilization of antibodies to the test strip.

13. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Katz et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach the use of ligand/receptor system to immobilize the antibodies in the capture zone of the test strip.

See above for the teachings of Katz et al.

It would have been obvious to one of ordinary skill in the art to use the avidin/biotin system of Katz et al to immobilize the antibodies in the capture zone of the test strip of Lou et al. as modified by the teachings of Maggio et al, because the highly specific affinity avidin for biotin provides for improved immobilization of antibodies to the test strip.

14. Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Bunting.

See above for the teachings of Lou et al.

Lou et al differs from the instant invention in failing to teach the use of a receptor/hapten system for immobilizing the antibodies in the capture zone of the test strip.

Bunting (U.S. Patent 4,271,140) teach the use of a receptor/hapten system for immobilizing antibodies to a solid support (cols. 3-6).

It would have been obvious to one of ordinary skill in the art to use the receptor/hapten system of Bunting to immobilize the antibodies in the capture zone of Lou et al's test strip because the receptor/hapten system of Bunting provides the advantage of being able to recover bound analyte from the capture zone (col. 3, lines 36-46).

15. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Bunting.

See above for the teachings of Lou et al and Maggio et al.

Lou et and Maggio et al further differ from the instant invention in failing to teach the use of a receptor/hapten system for immobilizing the antibodies in the capture zone of the test strip.

See above for the teachings of Bunting.

It would have been obvious to one of ordinary skill in the art to use the receptor/hapten system of Bunting to immobilize the antibodies in the capture zone of Lou et al's test strip, as modified by the teachings of Maggio et al, because the receptor/hapten system of Bunting provides the advantage of being able to recover bound analyte from the capture zone (col. 3, lines 36-46).

Allowable Subject Matter

16. Claims 10, 15, 23, 62, 69, and 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. This is a CPA of applicant's earlier Application No. 08/812,616. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no. however. event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
February 21, 2000

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1200

T2046A [redacted] USU

EXHIBIT B

UNITED STA[redacted] DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

KBDow

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/812,616	03/06/97	BOEHRINGER H	12046-010500

HM12/0901

TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
CHIN, C	
ART UNIT	PAPER NUMBER
1641	16

DATE MAILED: 09/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

TOWNSEND & TOWNSEND & CREW

00 SEP -8 AM 10:34

RECEIVED

Response Due 12/01/00

[redacted]

Exhibit B
Page 1 of 12

PTO-90C (Rev. 2/95)

2 - Mail Copy

Office Action Summary	Application No. 08/812,616	Applicant(s) Boehringer et al
	Examiner Chris Chin	Group Art Unit 1641

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 4-23, 53, 56-63, 65-81, and 120-125* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *15, 23, 69, and 79* is/are allowed.

☒ Claim(s) *1, 4-14, 16-22, 53, 56-63, 65-68, 70-78, 80, 81, and 120-125* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. The office action dated 2/23/00 is vacated in favor of the following office action. The preliminary amendment that was originally filed on January 3, 2000 (a copy of which was received via FAX on March 3, 2000) has been entered.

Continued Prosecution Application

2. The request filed on 1/21/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/812,616 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

3. Applicant's election with traverse of Group I in Paper No.6 is acknowledged. The traversal is on the ground(s) that some of the groups are classified in the same class and subclass and thus would not create an undue burden on the examiner. This is not found persuasive because even though some of the groups are placed in the same class and subclass, the search for each of the groups require a different search strategy on commercial data bases since they recite some limitations that do not overlap. However, upon further consideration, claims 16-23, 53-81 and 120 will be examined along with claims 1-15 of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 4-23, 53, 56-63, 65-81, and 120-125 will be examined.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al.

Lou et al (Clin. Chem. 39/4, 619-624, 1993) disclose a method and chromatographic test strip for detection and quantitation of lipoprotein a (Lp(a)). As shown in Figure 1, the test strip comprises a sample loading area, conjugate pad, measurement region, and an end of assay indicator. The conjugate pad contains diffusible Lp(a) coated colloidal selenium particles. The measurement region contains immobilized monoclonal antibodies specific for Lp(a). The

antibodies are positioned in the measurement region in a ladder-bar format. An end of assay indicator is located at the end of the test strip. In use, the number of ladder bars shown in the measurement region provides an indication of the amount of Lp(a) present - see pages 619-621.

Lou et al differ from the instant invention in failing to teach configuring the disclosed test strip for sandwich immunoassays.

Maggio et al teach the advantages and disadvantages of competitive and sandwich immunoassays. Sandwich immunoassays obviate the need for antigen reagents which are required for competitive immunoassays (page 61). The antigen reagent in competitive immunoassays must be as pure as possible. Unlike in sandwich immunoassays where the labeled reagent is a labeled antibody which does not have to be highly purified (pages 184-185).

It would have been obvious to one of ordinary skill in the art to configure the test strip of Lou et al for sandwich immunoassays as taught by Maggio et al because Maggio et al teach that sandwich immunoassays provide the advantage of obviating the need for an antigen reagent, such as the Lp(a) required for the Lp(a) coated selenium particles in the conjugate pad of Lou et al. By configuring the test strip of Lou et al for a sandwich immunoassay, there would be no need for purification procedures to obtain highly purified Lp(a).

With respect to claim 120, it would have been obvious to one of ordinary skill in the art to place the test strip of Lou et al (or Lou et al as modified by the teachings of Maggio et al) in a test kit arrangement because test kits are well known in the art for their recognized advantages of convenience and economy.

7. Claims 7, 20, 59, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Weng et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach the use of particles to indirectly immobilize the antibodies in the capture zone(s) of the test strip.

Weng et al (U.S. Patent 4,740,468) teach the use of particles to indirectly immobilize antibodies to a specific reagent zone of a chromatographic test strip (col. 13, line 50, to col. 14, line 68).

It would have been obvious to one of ordinary skill in the art to use particles, as taught by Weng et al, to immobilize the antibodies in the capture zone of the test strip of Lou et al, as modified by the teachings of Maggio, because Weng et al show it to be conventional in the art to immobilize antibodies to a chromatographic test strip via the use of particles. Moreover, particles provide the advantage of increased surface area so that more antibodies can be immobilized to the capture zone.

8. Claims 71 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Kang et al.

Notice of References Cited

Application No.	Applicant(s)		
08/812,616	Boehringer et al		
Examiner	Group Art Unit	Page 1 of 1	
Chris Chin	1641		

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	4,943,522	7/24/90	Eisinger et al	435	805
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N						
O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U		
V		
W		
X		

Exhibit B
Page 3 f 12

EXHIBIT C

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, DC 20231

NS Cassell
12046A0105000US

AUG 23 2001

RJH
Paper No. 20

In re Application of:
BOEHRINGER ET AL.
Serial No.: 08/812,616
Filed: March 06, 1997
For: Quantitative Lateral Flow Assays and Devices

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.181, filed June 28, 2001, to withdraw the holding of abandonment.

This application was filed as a continued prosecution application on January 21, 1999. On February 23, 2000, a final Office action was mailed to applicants. On September 1, 2000, a non-final Office action was mailed to applicants which vacated the February 23, 2000 Office action. The February 23, 2000 Office action was presumably vacated because it did not take into consideration a preliminary amendment filed on January 6, 2000 (certificate of mailing dated January 3, 2000). The original amendment filed January 6, 2000 is present in the file as are several copies that were faxed to the Office. On May 8, 2001, a notice of abandonment was mailed to applicants which indicated that the application was abandoned for failure to timely file a proper response to the September 1, 2000 Office action. On June 28, 2001, the present petition was filed.

Petitioner asserted that the abandonment should be withdrawn since a response was timely filed with a three month extension of time on March 5, 2001 (certificate of mailing dated March 1, 2001). Along with the petition, petitioner filed a copy of the response and the three month extension of time.

A review of the file revealed that the response and three month extension of time filed on March 5, 2001 were present in the application. It appears that the problem arose because the examiner thought that the March 5, 2001 response was merely a copy of the January 6, 2000 amendment and not a response to the September 1, 2000 Office action. In fact, the word "Duplicate" was written by someone on the top of the paper. Hence, the examiner abandoned the application for failure to respond to the September 2, 2000 Office action. However, the timely filing of the March 5, 2001 paper and extension of time and their presence in the application does not dispose of the issue of abandonment. For abandonment to be withdrawn, the March 5, 2001 paper must

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nit: 1600

ner fully responsive to the September 1, 2000 Office action or at least a *bone fide* attempt to ce the application to a final action. See 37 CFR 1.111, 37 CFR 1.135(c), and MPEP 2-714.03.

etermine whether the March 5, 2001 paper constitutes a proper response or a *bone fide* npt to respond to the September 1, 2000 Office action a comparison of the paper with the ary 6, 2000 amendment was done. This comparison revealed the following:

ne March 5, 2001 paper does indicate on page 1 that it is in response to the September 1, 2000 ice action whereas the January 6, 2000 paper indicates that it is a preliminary amendment.

he amendments on page 1 through page 6, line 9, of the March 5, 2001 paper are identical to amendments in the same place of the January 6, 2000 paper. Thus, it is not seen why such endments were necessary to present in the March 5, 2001 paper.

The March 5, 2001 paper attempted to add claims 121-143 whereas the January 6, 2000 paper dded claims 121-125. Thus, the attempt to add claims 121-143 was confusing especially since laims 121-123 and 131 were identical to claims 122-125 as added by the January 6, 2000 paper.

-The "REMARKS" section of the March 5, 2001 paper only differed from the "REMARKS" ection of the January 6, 2000 paper to a very minor degree. Two examples are: the claim numbers that should be pending listed in the second paragraph of the "REMARKS" section in both papers; and, the explanation as to what the Lou reference teaches (the explanation appears under section II in both papers). There is no real difference in the substance of the remarks of the two papers.

In addition, a comparison was done of the March 5, 2001 paper with the September 1, 2000 Office action. This comparison revealed the following:

--The paper argued a rejection under 35 U.S.C. 112, second paragraph, that was never made in the Office action.

--The paper argued a rejection of claims 1, 2, 5, 6, 13, 14, 53, 54, and 58 under 35 U.S.C. 102 over Lou et al whereas the rejection made in the Office action was only of claims 124 and 125.

--The claims listed in arguing many of the other rejections do not correspond with the claims rejected by the examiner in the Office action.

--There are art rejections argued in the paper that do not appear in the Office action, e.g., Lou in view of Weng, Lou in view of Katz, and Lou in view of Bunting.

--The paper fails to address the rejection of claims over Lou et al in view of Maggio et al and further in view of Eisinger et al as set forth in the September 1, 2000 Office action.

--Page 17 of the paper indicated that applicants consider claims 10 and 62 as being allowed. However, the Office action rejected those claims as being unpatentable over Lou et al in view of Maggio et al and further in view of Eisinger et al.

In view of the above noted comparisons, it has reasonably been concluded here that the March 5, 2001 paper is not fully responsive to the September 1, 2000 Office action and that the March 5, 2001 paper does not even constitute a *bone fide* attempt to advance the application to a final action. See 37 CFR 1.111, 37 CFR 1.135(c), and MPEP 714.12-714.03. With no proper and timely response to the September 1, 2000 Office action, there is no proper reason to withdraw the holding of abandonment.

PETITION DENIED.

John Doll, Director
Technology Center 1600

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Exhibit D

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Box DAC
Assistant Commissioner for Patents
Washington, D.C. 20231

On November 7, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: [signature]

PATENT
Attorney Docket No.: 12046A-010500US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hans Boehringer et al.

Application No.: 08/812,616

Filed: March 7, 1997

For: QUANTITATIVE LATERAL FLOW ASSAYS AND DEVICES

Examiner: C. Chin

Art Unit: 1641

PETITION FOR REVIVAL OF AN APPLICATION ABANDONED UNINTENTIONALLY UNDER 37 C.F.R. §1.137(b)

Box DAC
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants petition to revive the above-identified application under 37 C.F.R. §1.137(b). The application was unintentionally abandoned for failure to submit a proper response to the Office Action mailed September 1, 2000.

The entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. §1.137(b) was unintentional.

The Commissioner is authorized to deduct the petition fee, pursuant to 37 C.F.R. §1.17(m) of $640.00 from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit overpayment to, this same deposit account.

PATENT

Concurrent with the filing of this Petition, and in response to the Office Action mailed September 1, 2000, Applicants submit an Amendment which is believed to put the Application in condition for allowance, thus satisfying 37 C.F.R. §1.137(b)(1).

This Petition is submitted in duplicate.

Respectfully submitted,

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PA 3177190 v1

Exhibit E

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Box DAC
Assistant Commissioner for Patents
Washington, D.C. 20231

On December 7, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: [signature]

PATENT
Attorney Docket No.: 12046A-010500US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: C. Chin
Hans Boehringer et al.	Art Unit: 1641
Application No.: 08/812,616	AMENDMENT
Filed: March 7, 1997	
For: QUANTITATIVE LATERAL FLOW ASSAYS AND DEVICES	

Box DAC
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed September 1, 2000, please amend the above-identified application as follows. A Petition for Revival of an Application Abandoned Unintentionally Under 37 CFR §1.137(b) accompanies this response.

IN THE CLAIMS:

Please amend claim 17 as follows.

17. (Amended) The method of claim 16, wherein the labeled first spb member is an antibody capable of binding the analyte.

Please amend claim 77 as follows.

77. (Twice Amended) The device of claim 72, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

Please amend claim 121 as follows.

121. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of claim 72, a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

Please amend claim 122 as follows.

122. The device of claim 72, wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.

Please amend claim 123 as follows.

123. (Amended) The device of claim 61 wherein the ligand is a hapten and the receptor is a complement to the hapten.

Please add claim 126 as follows.

126. (New) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and a single capture zone, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and the capture zone comprises at least a second sbp member uniformly immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the capture zone whereby the pattern shows a distance traversed by the label al ng the single capture zone; and

correlating a pattern of label accumulated in the capture zone to the amount of analyte in the sample.

Please add claim 127 as follows.

127. (New) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

a capture zone;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and the capture zone comprises at least a second sbp member uniformly immobilized in the capture zone, the second sbp member being complementary to the analyte.

Please add claim 128 as follows.

128. (New) The method of claim 1, wherein the labeled first sbp member is an antibody capable of binding the analyte.

Claim 17 is amended to correct a minor inadvertent typographical error.

Support for the amendment to claim 77 can be found throughout the specification, and at least at page 6, lines 15-19, and Fig. 1.

Claim 121 is amended to perfect a claim dependency. When originally filed, claim 121 inadvertently referred to the device of claim 74, instead of the device of claim 72. This amendment corrects the dependency.

Claim 122 is amended to conform the claim to a competitive format, instead of a sandwich format. Support for this amendment can be found throughout the specification, and at least at page 4, lines 30-35.

Claim 123 is amended to perfect the claim dependency. When originally filed, claim 123 inadvertently depended from claim 121, instead of the device of claim 61. This amendment corrects the dependency.

Support for new claim 126 can be found throughout the specification, and at least at claim 1 as originally filed, and claim 14.

Support for new claim 127 can be found throughout the specification, and at least at claim 53 as originally filed, and claim 68.

Support for new claim 128 can be found throughout the specification, and at least at page 4, lines 30-35 and page 39, lines 22-37.

REMARKS

Claims 1, 4-23, 53, 56-63, 65-81, and 120-128 are pending. Claims 2, 3, 24-52, 54, 55, 64, and 82-119 were previously canceled. Claims 17, 77, and 121-123 have been amended. Claims 126-128 have been added. Claims 15, 23, 69, and 79 are allowable. Reconsideration of the pending claims is respectfully requested. The paragraph numbering follows that of the Office Action.

Rejections Under 35 U.S.C. §103

¶6. Claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80, and 120-122 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Lou et al., Clin. Chem. 39(4):619-24 (1993) ["Lou"] in view of Maggio et al., Edward T. Maggio, Ed., pp. 61, 184-5 (1987) [Maggio"]. This rejection is respectfully traversed.

Lack of Motivation To Combine the Cited References

To establish a *prima facie* case of obviousness, the Office must show that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to the artisan, to modify the reference or to combine references to arrive at the claimed invention. Further, there must be evidence suggesting the modification would be successful. Applicants respectfully submit such a showing has not been made.

Briefly, claim 1 is directed to a method of quantifying analyte in a sample by (1) providing a lateral flow matrix that includes a sample receiving zone, a labeling zone containing diffusively bound a labeled first sbp member complementary to the analyte, and one or more serially oriented capture zones containing an immobilized second sbp member complementary to the analyte, (2) contacting sample with the sample receiving zone, (3) observing a pattern of label at the capture zones, and (4) correlating the pattern to an amount of analyte in the sample.

In contrast, Lou reports a one step competitive assay for measuring Lp(a) in plasma, including the steps of (1) providing a test strip that includes a sample loading area, a conjugate pad containing Lp(a)-coated colloidal selenium, and a series of measurement regions containing immobilized Lp(a)-specific monoclonal antibody, (2) applying serum, plasma, or whole blood to the sample loading area, (3) observing the number of measurement regions seen, and (4) correlating the number of regions seen to a concentration of Lp(a) protein in the sample. Yet Lou fails to teach certain elements of the claimed invention. For instance, Lou does not disclose an assay that provides a labeling zone containing a labeled first sbp member complementary to the analyte.

Maggio discusses a conventional enzyme immunoassays in both the competitive and sandwich formats. The conventional sandwich format includes the steps of (1) reacting the analyte with immobilized antibody, (2) washing the matrix, (3) reacting the washed matrix with an enzyme-antibody conjugate, (4) washing the matrix again, and (5) quantitating the enzyme reaction.

The Examiner suggests it would have been obvious to the artisan to modify the one-step competitive assay of Lou with the conventional sandwich format enzyme immunoassay of Maggio to arrive at the presently claimed invention because Maggio teaches that sandwich assays have the advantage of obviating the need for an antigen reagent. Applicants respectfully submit, however, that this analysis ignores certain disadvantages of the sandwich enzyme immunoassay observed by Maggio. For instance, Maggio reports that the sandwich format requires an additional wash step. Thus, there is ambiguity regarding the motivation to combine the references.

What is more, Applicants submit there are important differences between Maggio and Lou that fail to make their combination obvious. First, the conventional assays discussed by Maggio are performed in single wells. These assays have no zones, and do not involve reagents flowing on a strip. Second, the conventional assays of Maggio involve multiple wash steps, in contrast to the one-step format of Lou. Applicants submit there is no teaching or suggestion in Maggio that would motivate the artisan to take the sandwich assay format from Maggio and apply it to the one-step test strip assay of Lou. Nor is there teaching in Lou motivating the artisan to take the sandwich assay format from Maggio and apply it to the one-step test strip assay of Lou.

It is well established that simply because references can be combined, does not mean the resulting combination is obvious, unless the references also suggest the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicants respectfully submit that no such desirability of the combination is suggested by the references.

Thus, Applicants maintain that the cited references fail to teach or even remotely suggest that a sandwich format used in a conventional enzyme immunoassay should similarly be used in a lateral flow assay. The Office Action has not established a motivation to combine the one-step assay of Lou with the conventional enzyme immunoassay of Maggio to arrive at the presently claimed invention.

Cited References Fail To Provide Expectation of Success

Applicants respectfully submit that the Office Action has not provided evidence that the proposed modification of Lou by Maggio would successfully result in the claimed invention.

As noted above, while Lou discusses a one step competitive test strip assay, Maggio discusses conventional enzyme immunoassays that require wash steps. Yet each of the cited references fail to teach that sandwich enzyme immunoassays can be successfully adapted for use in a lateral flow format. Further, each fails to teach that sandwich enzyme immunoassays can be successfully adapted for use in a lateral flow format that quantifies an amount of analyte in a sample.

Additionally, Maggio is ambivalent about the advantages and disadvantages of competitive and sandwich enzyme immunoassays. At best, the combination of Lou (one-step competitive assay for quantifying analyte) with Maggio (conventional multi-step competitive and sandwich assays) may possibly provide the artisan with an invitation to vary the parameters by *trying* a lateral flow sandwich assay for quantifying analyte. But this also is insufficient; the combination does not provide the artisan with a reasonable expectation of success of arriving at the claimed invention.

What is more, Lou actually reports unexplained discrepancies between a conventional sandwich enzyme immunoassay (Terumo) and their competitive one-step assay. See Lou at page 622, right column, second to last paragraph. The Terumo sandwich assay is discussed further at page 621, left column, last paragraph. Consequently, it is respectfully submitted that Lou in fact casts further doubt that the artisan would reasonably expect the combination of the cited references to successfully result in the presently claimed invention. The cited references fail to demonstrate that the sandwich assay of Maggio can successfully be translated to the one-step quantitative assay of Lou.

Applicants also note that the combination of cited references has been known to the public since 1993. Yet to Applicants knowledge, at the time the present application was filed, there were no published reports of any lateral flow quantitative assay comparable to that developed and presently claimed. During the period between 1993 and 1997 substantial research related to lateral flow assays was carried out, and efficient methods for performing lateral flow quantitative assays would have been welcomed by the scientific and medical communities. Applicants submit that the absence of scientific literature of any report of the allegedly obvious method is a classical indicium unobviousness.

Relatedly, according to MPEP 2141.01 (III), the content of the cited references must be considered at the time the invention was made, to avoid hindsight. The Office must "occupy the mind of one skilled in the art who is presented with the references, and who is normally guided by the then-accepted wisdom in the art."

Applicants respectfully submit that at the time the invention was made, the artisan would not have found the presently claimed invention to be obvious in light of the cited references.

Based on the above, Applicants submit the Office Action has not shown a motivation to combine the cited references to arrive at a method of quantifying analyte in a sample by (1) providing a lateral flow matrix that includes a sample receiving zone, a labeling zone containing diffusively bound a labeled 1st sbp member complementary to the analyte, and one or more serially oriented capture zones containing an immobilized 2nd sbp member complementary to the analyte, (2) contacting sample with the sample receiving zone, (3) observing a pattern of label at the capture zones, and (4) correlating the pattern to an amount of analyte in the sample. Further, the Office Action has not shown that artisan, at the time the invention was made, would reasonably expect the combination of references to successfully result in such a method. Applicants respectfully submit, therefore, that *prima facie* obviousness has not been established. Withdrawal of this rejection is respectfully requested.

Claims 4-6, 8, 11, 13, and 14 depend from, and incorporate the elements of, claim 1. Applicants respectfully submit that since a *prima facie* case of obviousness has not been established for claim 1, it is requested that this rejection be withdrawn from these claims as well.

Claim 14 is directed to the quantitative sandwich assay of claim 1, further providing the step of observing a distance traversed by the label along a single capture zone. The assays of Lou and Maggio have been discussed above; each fail to disclose this claimed feature.

To establish a *prima facie* case of obviousness, the Examiner must show that the prior art reference, or references when combined, must teach or suggest all the claim limitations. Applicant respectfully submits this showing has not been made with respect to claim 14. Specifically, each of Lou and Maggio fail to teach an assay that includes the step of observing a distance traversed by a labeled first sbp member along a

single capture zone. Accordingly, withdrawal of this rejection as applied to claim 14 is respectfully requested.

Generally, claim 16 is directed to a method of quantifying analyte in a sample by (1) providing a lateral flow matrix that includes a sample receiving zone, a labeling zone containing diffusively bound a labeled first sbp member complementary to the analyte, and one or more serially oriented capture zones containing an immobilized second sbp member that is analogous to the analyte, (2) contacting sample with the sample receiving zone, (3) observing a pattern of label at the capture zones, and (4) correlating the pattern to an amount of analyte in the sample. The assays of Lou and Maggio have been discussed above; yet each fail to disclose a lateral flow assay providing a second sbp member that is analogous to the analyte.

Absent a showing that Lou or Maggio teach or suggest a lateral flow assay providing this claimed element, Applicants submit that a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of this rejection as applied to claim 16 is respectfully requested.

Claims 17-19, 21, and 22 depend from, and incorporate the elements of, claim 16. Applicants respectfully submit that since a *prima facie* case of obviousness has not been established for claim 16, it is requested that this rejection be withdrawn from these claims as well.

Briefly, claim 53 is directed to an assay device corresponding to the method of claim 1. For many of the reasons given above with respect to claim 1, Applicants submit that the Office Action has not made a showing that claim 53 is *prima facie* obvious.

Claims 56-58, 60, 63, 65-68, 71, and 122 depend from, and incorporate the elements of, claim 53. Applicants respectfully submit that since a *prima facie* case of obviousness has not been established for claim 53, it is requested that this rejection be withdrawn from these claims as well.

Generally, claim 72 is directed to an assay device corresp nding to the method of claim 16. For many f the reasons given above with respect to claim 16,

Applicants submit that the Office Action has not made a showing that claim 72 is *prima facie* obvious.

Claims 73-75, 77, 78, and 80 depend from, and incorporate the elements of, claim 72. Applicants respectfully submit that since a *prima facie* case of obviousness has not been established for claim 72, it is requested that this rejection be withdrawn from these claims as well.

Claim 120 is directed to an assay kit corresponding to the device of claim 53. Applicants respectfully submit that for many of the reasons cited above with respect to claim 53, a *prima facie* case of obviousness has not been established for claim 120. Withdrawal of this rejection is respectfully requested.

As amended, claim 121 is directed to an assay kit corresponding to the device of claim 72. For many of the reasons cited above with respect to claim 72, Applicants submit that a *prima facie* case of obviousness has not been established for claim 121. Withdrawal of this rejection is respectfully requested.

¶7. Claims 7, 20, 59, and 76 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Lou in view of Maggio as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80, and 120-122, and further in view of US 4,740,468 to Weng et al. ["Weng"]. This rejection is respectfully traversed.

In brief, claims 7, 20, 59, and 76 are directed to assays and devices having the same elements recited in claims 1, 16, 53, and 72, respectively, wherein the assay further provides a second sbp member that is attached to an immobilized particle. Lou and Maggio are described above. Weng discusses an assay having an sbp member attached to an immobilized particle. Applicants submit that because a *prima facie* case of obviousness based on Lou and Maggio has not been established with regard to base claims 1, 16, 53, and 72 (see ¶6), this rejection in view of Weng is similarly improper. Withdrawal of the rejection is respectfully requested.

¶8. Claims 71 and 81 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Lou in view of Maggio as applied to claims 1, 4-6, 8, 11, 13, 14,

16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80, and 120-122, and further in view of US 5,559,041 to Kang et al. ["Kang"]. This rejection is respectfully traversed.

Claims 71 and 81 are directed to assay devices having the same elements recited in claims 70 and 80, respectively, wherein the device further provides a common sample receiving zone. Kang discusses an assay having a common sample receiving zone. Applicants submit that because a *prima facie* case of obviousness based on Lou and Maggio has not been established with regard to base claims 70 and 80 (see ¶6), this rejection in view of Kang is similarly improper. Withdrawal of the rejection is respectfully requested.

¶9. Claims 9 and 61 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Lou in view of Maggio as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80, and 120-122, and further in view of US 4,496,654 to Katz et al. ["Katz"]. This rejection is respectfully traversed.

Claims 9 and 61 are directed to assays having the same elements recited in claims 1 and 53, respectively, wherein the assay further provides a second sbp member labeled with a ligand and immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone. Katz discusses an assay having a biotinylated antibody attached to a capture zone via an avidin receptor. Applicants submit that because a *prima facie* case of obviousness based on Lou and Maggio has not been established with regard to base claims 1 and 53 (see ¶6), this rejection in view of Katz is similarly improper. Withdrawal of the rejection is respectfully requested.

¶10. Claims 12, 64, and 123 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Lou in view of Maggio as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80, and 120-122, and further in view of US 4,271,140 to Bunting. This rejection is respectfully traversed.

Claim 64 was previously canceled. Claim 12, and claim 123 as amended, are directed to assays having the same elements recited in claims 9 and 61, respectively, wherein the assay further provides a second sbp member labeled with a hapten and immobilized on the capture zone by a receptor for the hapten coimmobilized on the

capture zone. Bunting reports a double receptor, specific binding assay having a first receptor specific for a second receptor, the second receptor capable of binding a ligand.

Applicants submit that because a *prima facie* case of obviousness based on Lou and Maggio has not been established with regard to base claims 9 and 61 (see ¶9), this rejection in view of Bunting is similarly improper. Withdrawal of the rejection is respectfully requested.

¶11. Claims 10 and 62 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Lou in view of Maggio as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80, and 120-122, and further in view of US 4,943,522 to Eisinger et al. ["Eisinger"]. This rejection is respectfully traversed.

In brief, claims 10 and 62 are directed to assays having the same elements recited in claims 1 and 53, respectively, wherein the assay further provides a second sbp member that is an antibody against a complex formed between the analyte and the first sbp member. Eisinger discusses an assay having an antibody against a complex formed between an analyte and a binding member.

Applicants submit that because a *prima facie* case of obviousness based on Lou and Maggio has not been established with regard to original base claims 1 and 53 (see ¶6), this rejection in view of Eisinger is similarly improper. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

¶13. Claims 124 and 125 were rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Lou. This rejection is respectfully traversed.

Briefly, claim 124 is directed to an assay method, and claim 125 to an assay device, for quantifying analyte in a sample by providing, *inter alia*, a first sbp binding member that includes a visually detectable particulate or nonparticulate label, wherein the particulate label comprises dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

Lou discusses an assay using colloidal selenium (a nonmetallic colloid) as a label. In contrast, claims 124 and 125 are drawn to exclude nonmetallic colloids. According to the MPEP 2131, to anticipate a claim, the reference must teach every element of the claim. Based on the above, Applicants submit that Lou fails to teach every element of claims 124 and 125. Withdrawal of this rejection is respectfully requested.

Allowable Subject Matter

¶14. The Examiner has indicated claims 15, 23, 69, and 79 are allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**" Also attached, for the Examiner's convenient reference, are all the pending claims. This attachment is captioned "**Appendix of Pending Claims.**"

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 17 has been amended as follows.

17. (Amended) The method of claim 16, wherein the labeled first spb member is an [a] antibody capable of binding the analyte.

Claim 77 has been amended as follows.

77. (Twice Amended) The device of claim 72, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

Claim 121 has been amended as follows.

121. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of claim 72 [74], a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

Claim 122 has been amended as follows.

122. (Amended) The device of claim 72 [53], wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.

Claim 123 has been amended as follows.

123. (Amended) The device of claim 61 [121] wherein the ligand is a hapten and the receptor is a complement to the hapten.

Claim 126 has been added as follows.

126. (New) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and a single capture zone, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and the capture zone comprises at least a second sbp

member uniformly immobilized in the capture zone, th second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the capture zone whereby the pattern shows a distance traversed by the label along the single capture zone; and

correlating a pattern of label accumulated in the capture zone to the amount of analyte in the sample.

Claim 127 has been added as follows.

127. (New) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

a capture zone;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and the capture zone comprises at least a second sbp member uniformly immobilized in the capture zone, the second sbp member being complementary to the analyte.

Claim 128 has been added as follows.

128. (New) The method of claim 1, wherein the labeled first sbp member is an antibody capable of binding the analyte.

APPENDIX OF PENDING CLAIMS

1. (Amended) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

4. The method of claim 1, wherein the labeled first sbp member is an antiligand capable of binding the analyte.

5. The method of claim 1, wherein the first sbp member includes a visually detectable label.

6. The method of claim 5, wherein the visually detectable label comprises a visible particulate label.

7. The method of claim 1, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

8. (Amended) The method of claim 1, wherein the second spb member is a ligand capable of binding the analyte.

9. The method of claim 1, wherein the second sbp member is labeled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

10. (Amended) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

11. The method of claim 1, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

12. The method of claim 9, wherein the ligand is a hapten and the receptor is a complement to the hapten.

13. The method of claim 1, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

14. The method of claim 1, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

15. (Amended) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

16. A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of labeled first sbp member that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

17. (Amended) The method of claim 16, wherein the labeled first spb member is an antibody capable of binding the analyte.

18. The method of claim 16, wherein the labeled first sbp member includes a visually detectable label.

19. The method of claim 18, wherein the visually detectable label comprises a visible particulate label.

20. The method of claim 16, wherein the second sbp member is attached to particles and the particles are immobilized in the one or more capture zones.

21. The method of claim 18, wherein the lateral flow matrix comprises a plurality of capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

22. The method of claim 18, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

23. (Amended) A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of labeled first sbp member that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the ne or more capture zones to the amount of analyte in the sample;

wherein the labeled first sbp member includes a visually detectable label;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

53. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte.

56. (Amended) The device of claim 53, wherein the labeled first sbp member is an antibody capable of binding the analyte.

57. (Amended) The device of claim 53, wherein the first sbp member includes a visually detectable label.

58. (Amended) The device of claim 57, wherein the visually detectable label comprises a visible particulate label.

59. (Amended) The device of claim 53, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

60. (Amended) The device of claim 53, wherein the second spb member is an antibody capable of binding the analyte.

61. (Amended) The device of claim 53, wherein the second sbp member is labeled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

62. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

63. (Amended) The device of claim 53, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

65. (Amended) The device of claim 53, wherein the analyte is human IgE.

66. (Amended) The device of claim 65, wherein the first sbp member is goat anti-human IgE and the second sbp member is mouse monoclonal anti-human IgE.

67. (Amended) The device of claim 53, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

68. (Amended) The device of claim 53, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

69. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

70. (Amended) The device of claim 53, wherein the device comprises a plurality of discrete lateral flow matrices.

71. (Amended) The device of claim 70, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

72. A device for determining an amount f an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte.

73. (Amended) The device of claim 72, wherein the labeled first spb member is an antibody capable of binding the analyte.

74. (Amended) The device of claim 72, wherein the labeled first sbp member includes a visually detectable label.

75. (Amended) The device of claim 74, wherein the visually detectable label comprises a visible particulate label.

76. (Amended) The device of claim 72, wherein the second sbp member is attached to particles and the particles are immobilized in the one or more capture zones.

77. (Twice Amended) The device of claim 72, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

78. (Amended) The device of claim 72, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

79. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

80. (Amended) The device of claim 72, wherein the device comprises a plurality of discrete lateral flow matrices.

81. The device of claim 80, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

120. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of claim 53, a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

121. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of claim 72, a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

122. (Amended) The device of claim 72, wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.

123. (Amended) The device of claim 61 wherein the ligand is a hapten and the receptor is a complement to the hapten.

124. A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein said first sbp member includes a visually detectable particulate or nonparticulate label, said particulate label comprising dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

125. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein said first sbp member includes a visually detectable particulate or nonparticulate label, said particulate label comprising dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

126. (New) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and a single capture zone, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and the capture zone comprises at least a second sbp member uniformly immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the capture zone whereby the pattern shows a distance traversed by the label along the single capture zone; and

correlating a pattern of label accumulated in the capture zone to the amount of analyte in the sample.

127. (New) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

a capture zone;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and the capture zone comprises at least a second sbp member uniformly immobilized in the capture zone, the second sbp member being complementary to the analyte.

128. (New) The method of claim 1, wherein the labeled first sbp member is an antibody capable of binding the analyte.

Exhibit F

UNITED STATES PATENT AND TRADEMARK OFFICE

Request Reconsideration Due

REMINDER: 5/24/02

DUE DATE: 6/24/02

FINAL DUE DATE: 10/24/02

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APR 24 2002

OFFICE OF PETITIONS

In re Application of
Boehringer, et al.
Application No. 08/812,616
Filed: March 6, 1997
Attorney Docket No. 273102007800

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.137(b), filed on January 7, 2002 (Certificate of Mailing dated November 7, 2001), to revive the above-identified application.

The petition is **DISMISSED**.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition Under 37 CFR 1.137(b)." This is **not** a final agency decision within the meaning of 5 USC 704.

The above-identified application became abandoned for failure to timely file a proper response to the final Office action mailed September 1, 2000, which set a shortened statutory period for reply of three months. On March 5, 2001, petitioner (through previous counsel) filed an amendment, made timely by obtaining a three month extension of time and including a Certificate of Mailing dated March 1, 2001. A Notice of Abandonment was mailed on May 8, 2001. In response, petitioner filed a petition to withdraw the holding of abandonment on June 13, 2001, citing the timely filed amendment of March 5, 2001. However, this petition was denied in a decision mailed on August 23, 2001.[1] Accordingly, the above-identified application was abandoned as of March 2, 2001.

A grantable petition under 37 CFR 1.137(b) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.137(d).

[1] The petition was denied because it was determined that the March 5, 2001 amendment did not constitute a *bona fide* attempt to respond to the final Office action.

Application No. 08/812,616

The instant petition lacks item (1), the required reply.

With the instant petition, petitioner filed an amendment in response to the final Office action. The proposed reply to a final Office action required for consideration of a petition to revive must be either (1) a Notice of Appeal (and fee required by law); (2) an amendment that *prima facie* places the application in condition for allowance; (3) the filing of a continuing application under 37 CFR 1.53(b) or if applicable, 1.53(d); (4) a request for a continuing examination (RCE) under 37 CFR 1.114; or (5) if applicable, a 37 CFR 1.129(a) submission.

Petitioner's only submission, an amendment, has been determined by the examiner not to *prima facie* place the application in condition for allowance. Thus, petitioner has failed to submit the required reply.

In order for the application to be revived, petitioner must submit a required reply within the meaning of 37 CFR 1.137(b)(1). **Any renewed petition should be accompanied by a proper reply in the form of a Notice of Appeal, the filing of a continuation application or a RCE.** If petitioner fails to reply in the form of a Notice of Appeal (and fee), a proper continuing application, or a proper RCE, it may be construed as an intentional delay in presenting a grantable petition, which may adversely affect petitioner's ability to revive the abandoned application.

The Revocation and Power of Attorney filed on March 5, 2002 is acknowledged and made of record. Future correspondence concerning the above-identified application will be mailed to the above address of record.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box DAC
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Office of Petitions

By hand: Office of Petitions
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Crystal Plaza 4, Suite 3C23
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Telephone inquiries concerning this decision should be directed to the undersigned at (703) 305-0272.

Cliff Congo
Petitions Attorney
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

Exhibit F
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See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach a multi-test strip embodiment wherein all of the test strips contact a common sample receiving zone.

Kang et al (U.S. Patent 5,559,041) disclose a multizone chromatographic test strip for performing sandwich or competitive immunoassays. Figure 5 shows an embodiment wherein multiple test strips are configured around a common sample receiving zone (310) for the purpose of assaying for one or more analytes in a given sample (col. 4, line 67, to col. 5, line 21).

It would have been obvious to one of ordinary skill in the art to configure the test strips of Lou et al around a common sample receiving zone as taught by Kang et al because Kang et al teaches that such a configuration provides the advantage of being able to perform multiple assays on the same sample for one or more desired analytes.

9. Claims 9 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Katz et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach the use of ligand/receptor system to immobilize the antibodies in the capture zone of the test strip.

Katz et al (U.S. Patent 4,496,654) teaches the use of an avidin/biotin system for immobilizing antibodies to a solid support. Avidin is first immobilized to a solid support.

Biotinylated antibodies are then applied to the avidin coated solid support. The biotin portion of the biotinylated antibodies binds to the avidin to immobilize the antibodies to the solid support.

It would have been obvious to one of ordinary skill in the art to use the avidin/biotin system of Katz et al to immobilize the antibodies in the capture zone of the test strip of Lou et al, as modified by the teachings of Maggio et al, because the highly specific affinity avidin for biotin provides for improved immobilization of antibodies to the test strip.

10. Claims 12, 64, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Bunting.

See above for the teachings of Lou et al and Maggio et al.

Lou et and Maggio et al further differ from the instant invention in failing to teach the use of a receptor/hapten system for immobilizing the antibodies in the capture zone of the test strip.

Bunting (U.S. Patent 4,271,140) teach the use of a receptor/hapten system for immobilizing antibodies to a solid support (cols. 3-6).

It would have been obvious to one of ordinary skill in the art to use the receptor/hapten system of Bunting to immobilize the antibodies in the capture zone of Lou et al's test strip, as modified by the teachings of Maggio et al, because the receptor/hapten system of Bunting provides the advantage of being able to recover bound analyte from the capture zone (col. 3, lines 36-46).

11. Claims 10 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above and further in view of Eisinger et al.

See above for the teachings of Lou et al in view of Maggio et al.

The combination of Lou et al in view of Maggio et al differs from the instant invention in failing to teach the use of binding reagent in the detection that can bind to a complex of analyte and a binding reagent.

Eisinger et al (U.S. Patent 4,943,522) discloses a chromatographic immunoassay device. The device includes a detection zone which contains an immobilized specific binding reagent that binds to complexes of analyte and another specific binding reagent (col. 7, lines 61-66).

It would have been obvious to one of ordinary skill in the art to use a binding reagent that is specific for complexes of analyte and another specific binding reagent, as taught by Eisinger et al, in the device of Lou et al, as modified by Maggio et al, because Eisinger et al shows it to be well known and conventional in the art to use such binding reagents in the detection zone of chromatographic immunoassay devices, such as the device of Lou et al.

Claim Rejections - 35 U.S.C. § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 124 and 125 are rejected under 35 U.S.C. 102(b) as being anticipated by Lou et al.

See above for the teachings of Lou et al. Lou et al discloses a chromatographic immunoassay device for performing competitive immunoassays.

Allowable Subject Matter

14. Claims 15, 23, 69 and 79 are allowed.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
August 30, 2000

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641